

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research**

Pulmonary-Allergy Drugs Advisory Committee (PADAC)

November 18, 2009

Question for Discussion

Xolair dosing is based on serum IgE levels. Discuss the implications (if any) of dosing that could result in an increase in circulating levels of omalizumab-IgE immune complexes in patients with IgE levels above 500 IU/mL.

Voting Questions

1. Do the data provide substantial and convincing evidence that Xolair provides a clinically meaningful beneficial effect for the treatment of asthma in pediatric patients 6 to 11 years of age inadequately controlled despite the use of inhaled corticosteroids?
a) If not, what further efficacy data should be obtained?
2. Has the safety of Xolair been adequately assessed for the treatment of asthma in pediatric patients 6 to 11 years of age?
a) If not, what further safety data should be obtained?
3. Do the safety and efficacy data provide substantial and convincing evidence to support approval of Xolair for the treatment of asthma in patients 6 to 11 years of age with moderate to severe persistent asthma whose symptoms are inadequately controlled with inhaled corticosteroids?
a) If not, what additional information is necessary to support approval?